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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,914	12/28/2001	Yoshihide Murakami	Q67950	2679
7590 03/17/2004				
SUGHRUE MION, PLLC 2100 Pennsylvania Avenue, NW Washington, DC 20037-3213			EXAMINER CHANG, VICTOR S	
			ART UNIT 1771	PAPER NUMBER

DATE MAILED: 03/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/028,914	MURAKAMI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Victor S Chang	1771	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                         |                                                                             |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                                |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____                                                             | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. The Examiner has carefully considered Applicants' remarks filed on 1/30/2004. Applicants' request for reconsideration has been entered. In particular, Applicants' argument during an interview on 3/9/2004 that the Advisory dated 2/25/04 was incorrectly directed to a previously submitted preliminary amendment, while the after-final response is only a request for reconsideration, is persuasive. The Examiner apologizes for the inadvertent error.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Rejections not maintained are withdrawn. In particular, Applicants' argument that "there is an embodiment which literally falls within the scope of claim 1 of the present application and does not literally fall within the scope of claim 4 of the parent patent. As a result, statutory double patenting under 35 U.S.C. 101 does not exist" (Response, page 2, bottom paragraph) is persuasive. As such, the rejection in section 4 of Paper No. 0925 is withdrawn. However, Applicants' argument is moot in view of the new grounds of rejection as follows.

### ***Terminal Disclaimer***

4. The terminal disclaimer filed on 1/30/2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent 6,372,339 has been reviewed and is accepted. The terminal disclaimer has

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been recorded. In view of the terminal disclaimer, the obviousness-type double patenting rejection in section 5 of Paper No. 0925 is withdrawn.

### ***Specification***

5. The disclosure is objected to because of the following informalities:

At page 4, lines 3-4, the disclosure "a mixture of the elastomer resin and a polymer which is higher in elasticity than the elastomer resin and has a water absorption ability" is clearly inconsistent with the description at page 4, lines 15-16 "a hydrophilic polymer having a tensile modulus of elasticity higher than that of the elastomer resin". For the purpose of this Office action, it is presumed that latter description is correct, so as to be consistent with the recitation of claim 1.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

6. Claims 1-9, 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a substrate film comprising a thermoplastic block copolymer and polyvinyl pyrrolidone, does not reasonably provide enablement for a substrate film comprising an "elastomer" and a "hydrophilic polymer". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

More particularly, since the Specification discloses only an elastomer of thermoplastic block polymer (page 4, lines 19-20), the claimed genus in claim 1 "an elastomer resin" is considered to be too broad and in excess of provided enablement in the Specification. Similarly, since the Specification discloses only polyvinyl pyrrolidone meets the requirements of tensile modulus of elasticity higher than that of the elastomer resin used, and also a high water absorption rate (page 9, line 21 to page 10, line 8), the claimed genus in claim 1 "a hydrophilic polymer" is also considered to be too broad and in excess of provided enablement. It should be noted that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice ... by functional characteristics coupled with a known or disclosed correlation between function and structure ... sufficient to show the applicant was in possession of the claimed genus. If a representative number of adequately described species are not disclosed for a genus, the claim to that genus must be rejected as lacking adequate written description under 35 U.S.C. 112, first paragraph. See MPEP § 2163.IIA3(a)ii.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bezwada et al. (US 5607687) in view of Webster (US 4541426).

Bezwada's invention is directed to a bioabsorbable polymeric material and blends thereof and more particularly to absorbable surgical products made from such polymers and blends thereof (column 1, lines 11-14). The blends comprises polyoxaesters and polyether polyurethanes, polyester polyurethanes, polyvinyl pyrrolidone, etc., and combinations thereof (column 2, lines 17-67). Useful embodiments made of the polymer blend include sheets for areas where the skin and underlying tissues are damaged or surgically removed, i.e., wound dressing (column 6, lines 38-64).

For claim 1-4, 6 and 8, Bezawa lacks express teachings that the hydrophilic polymer has a higher tensile modulus than the elastomer resin, and the blend is suitable as a substrate film of an adhesive sheet. However, it is believed that polyvinyl pyrrolidone inherently has a higher modulus than the thermoplastic block copolymer such as polyether polyurethanes. Further, it is noted that Webster's invention is directed to a dressing suitable for application to lesions of the skin (i.e., wound dressing) which comprises a conformable apertured film. The film consists of two layers laminated together, the first layer which is the lesion contacting layer is formed from a material which swells in contact with water (Abstract). Suitably the first layer which contacts the wet surface of the lesion will be formed from a hydrophilic polymer, such as films of blends of hydrophilic polymers including hydrophilic polyurethane with cellulosic derivatives, polyurethane with polyvinyl pyrrolidone, polyvinyl alcohol with polyvinyl

pyrrolidone and blends of hydrophilic and hydrophobic polyether-polyamides. Aptly such a hydrophilic polymer will contain between 5 and 95% by weight water when hydrated (column 2, line 49 to column 3, line 2). An adhesive may be applied over the entire surface of the first layer so that when in use the dressing is adhered to the intact skin (column 5, lines 63-65). As such, it would have been obvious to one of ordinary skill in the art to combine the teachings of Bezawa and Webster to form a wound dressing sheet which comprises a thermoplastic block polymer such as polyether polyurethanes and a hydrophilic polymer such as polyvinyl pyrrolidone, motivated by the desire to obtain a wound dressing which can be highly hydrated (Webster, column 2, lines 52-55).

For claims 5 and 7, Bezawa and Webster lack an express teaching of the weight ratio between the hydrophilic polymer and elastomer. However, since the scope of the invention is essentially the same, in particular Webster teaches 5-95% hydration as set forth above, it is believed that a suitable weight ratio is either inherently disclosed, or an obvious optimization in the absence of unexpected results, motivated by the desire to obtain a suitable hydration property.

For claim 9, similarly, although Bezawa and Webster are silent about the tensile modulus of the film in dry and in water saturated state, since the scope of the invention is essentially the same, in particular Webster teaches 5-95% hydration as set forth above, it is believed that a suitable tensile modulus is either inherently disclosed, or an obvious optimization in the absence of unexpected results, motivated by the desire to obtain a suitable conformability of the wound dressing to the surface of skin.

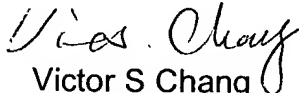
9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. In addition, the following references are cited of interest for making a backing layer having a high moisture transmission:

US 6103369 to Lucast et al. teaches a high moisture vapor transmission backing which is selected from materials containing a relatively high content of hydrophilic components including certain polyether block amides such as Pebax™ (Abstract and column 4, lines 1-15).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor S Chang whose telephone number is 571-272-1474. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel H Morris can be reached on 571-272-1478. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Victor S Chang  
Examiner  
Art Unit 1771